

Application Serial No. 10/058,963

REMARKS

I. Status Summary

Claims 21-32 are pending in the present application.

Claims 21, 24, 27, 30, and 31 presently stand rejected under the provisions of 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,911,807 to Burd (hereinafter referred to as "Burd").

Claims 21-27 and 30-32 presently stand rejected under the provisions of 35 U.S.C. § 102(b) as being anticipated by the publication of Strausbauch & Wettstein ("Fraction Collection with Micro-Preparative Capillary Electrophoresis," Handbook of Capillary Electrophoresis: Chapter 30 (second edition), (1997) pp. 841-864; hereinafter referred to as "Strausbauch et al.").

Claims 21, 27, 30, and 31 presently stand rejected under the provisions of 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,169,510 to Lunte *et al.* (hereinafter referred to as "Lunte et al.") in view of Burd or Strausbauch et al.

Claims 28 and 29 presently stand rejected under the provisions of 35 U.S.C. § 103(a) as being unpatentable over Burd or Strausbauch et al. in view of PCT Application No. WO 99/22228 to Karger *et al.* (hereinafter referred to as Karger et al.).

Claim 21 has been amended. Support for the amendment can be found throughout the specification as filed, including particularly at page 7, lines 1-4, page 7 lines 13-18; page 10, line 27, through page 11, line 5 and Figure 2. No new matter has been added as a result of the amendment to claim 21.

Reconsideration of the application as amended and based on the arguments set forth herein below is respectfully requested.

II. Rejection Under 35 U.S.C. § 102(b) as to Burd

Claims 21, 24, 27, 30, and 31 presently stand rejected under 35 U.S.C. § 102(b) as being anticipated by Burd.

The Patent Office asserts that the claims read on the operation of the embodiment of Burd illustrated in Figure 1. Specifically, the Patent Office contends

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that the "applying a sample" step recited in claim 21 reads on the function of sample reservoir 29. The Patent Office asserts that Burd teaches at column 3, lines 41-43: "A sample reservoir 29 is included in the block (28) for sample introduction."

The Patent Office further asserts that the "generating a migratory field" step recited in claim 21 reads on the function of cathode 15, anode 16, and power source 17 of Burd.

Regarding the "eluting" step and the "collecting" step recited in claim 21 and the "analyzing" step recited in claim 24, the Patent Office contends that Burd teaches at column 1, lines 50-54: "In the former, the segments are used to separate the species eluting from the larger capillary into separate receptacles, from which they may be separately recovered, detected, treated or otherwise processed."

Regarding the "interrupting the migratory field" step recited in claim 21, the Patent Office asserts that Burd teaches at column 4, lines 1-17: "In the embodiment shown in Figure 1, it will be noted that the capillary segments 18 are spaced apart at intervals around the cassette 12. The external openings 40 of the adjacent capillary segments are separated by portions of solid external wall 41. In the arrangement shown, these intervening wall portions close off the separation capillary 11 and interrupt the current path whenever the capillary segments 18 not in alignment between the separation capillary 11 and the outlet buffer reservoir 14. With the current path interrupted in this manner, the electrophoretic migration of solute species within the separation capillary 20 as well as all other portions of the apparatus is momentarily suspended while the cassette rotates further and brings the next capillary segment into position. Thus, no components of the sample are lost and the entire elution profile will be distributed among the various capillary segments in the cassette."

The Patent Office asserts that the "collecting step" recited in claim 21 includes the limitation "without using a detector to analyze the analyte prior to collection." The Patent Office contends that while the embodiment illustrated in Figure 1 shows a detector for analyzing the separated species prior to elution, this is an optional feature. The Patent Office asserts that Burd teaches at column 4, lines 59-61: "A

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variety of additional features may be incorporated into either of these systems. On line detection, for example, may be achieved..."

The Patent Office contends that the "repeating" step recited in claim 21 reads on Burd at column 1, lines 41-43: "The process may be repeated in an extended sequence, or as few times as once."

The Patent Office further contends that the limitation recited in claim 24 reads on Burd at column 1, lines 46-54: "The invention has two primary embodiments, one in which the interchangeable segments are positioned at the downstream end of the larger, main body of the capillary,...the segments are used to separate the species into separate receptacles, from which they may be separately recovered, detected, treated or otherwise processed."

Further, the Patent Office asserts that the limitations recited in claims 27 and 30 read on Burd at claim 14, lines 14-21: "(c) moving said first and second structural members with respect to each other to place said capillary segments one at a time in alignment with said separation capillary; and (d) upon alignment of each of said capillary segment with said separation capillary, imposing an electrical potential across the combined lengths of said separation capillary and the capillary segment aligned therewith."

Finally, the Patent Office asserts that the limitation recited in claim 31 reads on Burd since completely removing the electrical potential within the separation pathway constitutes "adjusting potential within the separation pathway."

After careful review of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

Applicants respectfully submit that the "interrupting step" of claim 21 has been amended to recite "interrupting the migratory field by removing the output end of the separation pathway from the collection well after the collecting." Support for the amendment can be found throughout the specification as filed, including particularly at page 7, lines 13-18; on page 10, line 27, through page 11, line 5; and in Figure 2. Applicants respectfully submit that the amended "interrupting step" of the instant application is novel in view of the disclosure recited in Burd.

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Figure 2 and page 7, lines 7-13, of the instant specification teach that the migratory field can be created by an electric potential applied by electrodes which can contact the input end and the output ends of the separation pathway. In some embodiments, a first electrode is coupled to the input end of the separation pathways and a second electrode is coupled to the collection reservoir, which includes a plurality of wells whereby the second electrode is coupled to each well. The output end of the separation pathway can be deposited within each successive well of the collection reservoir, thus setting up an electric field within the pathway. Fractions eluted from the separation pathway can migrate into the contacted well, and when the separation pathway is moved out of and away from the collection reservoir, the electric field is interrupted and migration is halted.

The Patent Office contends that Burd recites a system of capillary electrophoresis whereby intervening wall portions of a rotating cassette close off the separation capillary and interrupt the path of the current whenever the capillary segments are not in alignment with the separation capillary and the outlet buffer reservoir. The Patent Office asserts that with the current path interrupted in this manner, the electrophoretic migration of solute species within the separation capillary is suspended while the cassette rotates further and brings the next capillary segment into position. Therefore, applicants submit that the "interrupting step" of Burd relies on the disruption of the alignment between the separation capillary and the capillary segments, not on the physical removal of the output end of the separation pathway from the collection well, as recited in claims 21 and claims dependent therefrom.

As such, applicants respectfully assert that claim 21 is novel in light of the limitations of Burd. Applicants further assert that claims 24, 27, 30, and 31 directly depend from claim 21, and therefore are also novel in view of Burd. Thus, applicants respectfully request that the rejection of claims 21, 24, 27, 30, and 31 under 35 U.S.C. § 102(b) in view of Burd be withdrawn at this time.

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III. Rejection Under 35 U.S.C. § 102(b) as to Strausbauch et al.

Claims 21-27 and 30-32 presently stand rejected under 35 U.S.C. § 102(b) as being anticipated by Strausbauch et al.

The Patent Office contends that the “applying a sample” step, the “generating a migratory field” step, the “eluting an analyte” step and the “collecting the analyte” step recited in claim 21 and the limitation recited in claim 27 read on Strausbauch et al. because these steps occur in any preparative capillary electrophoretic separation, e.g. at page 842, lines 19-21: “The low volume of sample injection, requirement for fraction collection, and the unavoidable presence of high voltage (10-30 kV).”

Regarding the “interrupting” step recited in claim 21 and the “positioning” limitation recited in claim 30, the Patent Office contends that Strausbauch et al. teaches at page 846, lines 1-7: “The collection can be performed by manually changing the outlet (collection) vial at predetermined intervals with the applied voltage interrupted while either the outlet vial or capillary outlet is repositioned for each fraction. Because the electrophoresis buffer in the vial usually completes the high voltage circuit between the capillary and the outlet electrode, the operator may be exposed to a potential shock hazard. A preferred variation of the method is to have an automated fraction collector manipulate the outlet vials or capillary/outlet electrode assembly.”

While the Patent Office concedes that Strausbauch et al. does not explicitly state “collecting the analyte in a collection well without using a detector to analyze the analyte prior to collection” (i.e., absence of an on-column detector), the Patent Office argues that Strausbauch et al. teaches at page 849, lines 8-12: “Fraction collection routines can be programmed to collect a single component ‘window’ when the peak of interest and migration characteristics are known. Alternatively, fractions can be collected at fixed time intervals to collect the entire electrophoretic separation for recovery and assay of unknowns.” The Patent Office asserts that neither of these methods would require an on-column detector.

The Patent Office asserts that the “applying a sample” step and “generating a migratory field” step are inherent in any capillary electrophoretic separation. The

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Patent Office contends that the elements recited in claims 22 and 24 read on the second method of Strausbauch et al. above.

The Patent Office asserts that the elements recited in claim 23 and 32 read on the first method of Strausbauch et al. above.

Further, the Patent Office contends that claim 31 reads on Strausbauch et al. since complete removal of the potential from the capillary (zero potential) constitutes an adjustment of the potential in the capillary.

Regarding claims 25 and 26, the Patent Office recites the section of Strausbauch et al. entitled "Micro-Preparative CE of Nucleic Acids" and the section entitled "Micro-preparative CE of Peptides and Proteins."

After careful review of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

As noted in Section II, applicants again note that the "interrupting step" of claim 21 has been amended to recite "interrupting the migratory field by removing the output end of the separation pathway from the collection well after the collecting."

Applicants respectfully submit that Strausbauch et al. does not recite a method whereby the voltage is interrupted by removing the output end of the separation pathway from the collection well. Applicants respectfully submit that the language of Strausbauch et al. directs that the voltage is terminated as a first step, followed by a second step wherein the collection vial is changed, at page 846, lines 1-5: "The collection can be performed by manually changing the outlet (collection) vial at predetermined intervals with the applied voltage interrupted while either the outlet vial or capillary outlet is repositioned for each fraction."

As such, applicants contend that claim 21, which recites that the migratory field is interrupted by the physical removal and repositioning of the output end of the separation pathway into each collection well, is novel in view of the limitations of Strausbauch et al.

Applicants submit that claims 22-27, and 30-32 depend directly from claim 21, and as such, are novel over Strausbauch et al. Therefore, applicants respectfully

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request that the rejection of claims 21-27 and 30-32 under 35 U.S.C. § 102(b) be withdrawn at this time.

IV. Rejection Under 35 U.S.C. § 103(a) as to Lunte et al. in view of Burd or Strausbauch et al.

Claims 21, 27, 30, and 31 presently stand rejected under 35 U.S.C. § 103(a) as to Lunte et al. in view of Burd or Strausbauch et al.

The Patent Office asserts that all of the method steps recited in claim 21 read on the operation of the apparatus of Lunte et al., as illustrated in Figure 3, except for the "interrupting" step.

The Patent Office contends that while the "applying" step and "generating" step recited in claim 21 may not be explicitly recited in Lunte et al., they read on Lunte et al. because these steps occur in any capillary electrophoresis separation.

The Patent Office asserts that while the "collecting" step and "repeating" step are not explicitly recited in Lunte et al., these steps read on the operation of the embodiment of Lunte et al. as illustrated in Figure 3.

The Patent Office further asserts that the limitation that the collection occurs "without using a detector to analyze the analyte prior to collection" recited in claim 21 reads on Lunte et al. at column 2, lines 26-32: "Broadly speaking, the CE apparatus hereof includes an elongated electrophoretic capillary tube assembly of length (e.g., 2 meter) required for the separation of interest. One end of the tube is designed for connection with a power supply for applying a high voltage across the tube assembly; the opposite end of the tube assembly is adapted for coupling to an appropriate CE detector." The Patent Office further points to the assertion that the embodiment illustrated in Figure 3 lacks an on-column detector.

The Patent Office concedes that Lunte et al. is silent concerning interrupting the "migratory field" while one collection vial is exchanged for another. However, the Patent Office contends that it is well known in the CE art to temporarily interrupt the electric field when exchanging one collection vial for another. The Patent Office

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points to Burd and Strausbauch et al. as exemplary references that disclose this teaching.

Therefore, the Patent Office asserts it would have been obvious to one of ordinary skill at the time of the invention to interrupt the electric field through the capillary of Lunte et al. when changing collection vials because this would prevent loss of any of the separated species during the exchange of collection vials.

After careful review of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

The Patent Office admits that Lunte et al. does not recite an "interrupting step." Instead, the Patent Office contends that the combination of Lunte et al. in view of Burd or Strausbauch et al. supplies the "interrupting step". Applicants respectfully submit that, as discussed hereinabove, neither Burd nor Strausbauch et al. discloses an interrupting step as recited in claim 21. Accordingly, applicants respectfully submit that the combination Lunte et al. in view of Burd or Strausbauch et al. does not support a rejection of claim 21 under 35 U.S.C. § 103(a).

Additionally, applicants submit that claims 27, 30, and 31 depend directly from claim 21, and as such, are novel in view of the combination of Lunte et al. in view of Burd or Strausbauch et al.

Therefore, applicants respectfully request that the rejection of claims 21, 27, 30, and 31 under 35 U.S.C. § 103(a) be withdrawn at this time.

IV. Rejection Under 35 U.S.C. § 103(a) over Burd or Strausbauch et al. in view of Karger et al.

Claims 28 and 29 presently stand rejected under 35 U.S.C. § 103(a) over Burd or Strausbauch et al. in view of Karger et al. As to the teachings of Burd or Strausbauch et al., the Patent Office points to the rejections based on the references discussed above. The Patent Office asserts that Karger et al. is similar to Burd and Strausbauch et al. in that the detailed embodiment of Karger et al. is directed to capillary electrophoresis including fraction collection. However, the Patent Office contends that Karger et al. teaches at page 5, lines 20-30: "The system of the

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invention will now be described in detail using as an example a system for the separation of fluorescently labeled DNA fragments by capillary electrophoresis;...Any method of separation could be employed, including but not limited to capillary electrophoresis (CE)...and capillary liquid chromatography (CLC)."

The Patent Office contends that CLC involves creating a pressure differential between the ends of the capillary. The Patent Office asserts that this differential can be created by collecting one end of the capillary to either a source of pressure above ambient pressure ("applying a pressure to the separation pathway") or a source of pressure below ambient pressure ("drawing a vacuum in the separation pathway.")

Thus, the Patent Office argues it would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods of Burd or Strausbauch et al. for fraction collection in CLC even though the disclosure of Burd or Strausbauch et al. explicitly disclose CE because Karger et al. teaches that this is within the abilities of one skilled in the art.

After careful review of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

Applicants respectfully submit that claims 28 and 29 depend directly from claim 21. As discussed herein above, applicants respectfully submit that claim 21 is patentably distinguished over Burd or Strausbauch et al. Therefore, applicants respectfully submit that the combination of Karger et al. in view of Burd or Strausbauch et al. does not support a rejection of claims 28 and 29 under 35 U.S.C. § 103(a).

Therefore, applicants respectfully request that the instant rejection of claims 28 and 29 under 35 U.S.C. § 103(a) be withdrawn at this time.

CONCLUSIONS

Should there be any minor issues outstanding in this matter, the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

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Deposit Account

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number 50-0426.

Respectfully submitted,

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